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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,243	06/22/2001	H. Robert Horvitz	01997/211003	9113

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CLARK & ELBING LLP
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BOSTON, MA 02110

EXAMINER

MAYER, SUZANNE MARIE

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/888,243

Applicant(s)

HORVITZ ET AL.

Examiner

Suzanne M. Mayer

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-16 and 19 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13-16 is/are allowed.
- 6) ☒ Claim(s) 19 is/are rejected.
- 7) ☒ Claim(s) 12 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group 68, claims 13-16 and 19, in the reply filed on 04/07/2004 is acknowledged. The traversal is on the ground(s) that Groups 51-56, claims 12 and 18 in part, share the same classification and subclass and should be examined together with the elected Group 68. Furthermore, Applicants argue that the groups are inter-related and thus would not impose an under search burden upon the examiner.

The Examiner acknowledges that Group 53, drawn to claims 12 and 18 in part, are similar enough to warrant rejoining claim 12 (nn) to be considered in this examination and as a part of the elected Group 68. Groups 51-52 and 54-56, however, each are distinct and independent groups. Furthermore, the argument that Groups 51-56 and 68 are inter-related because that they all encode mutant ICE, CED-3, or NEDD-2 polypeptides having a highly conserved pentapeptide motif and that examining these groups on this basis would not present an undue search burden is not found persuasive. It is unpersuasive because examining the conserved pentapeptide motif with mutations at each position of would require searching 100 *different* sequences just to search the possible combinations of single substitutions at each position of the conserved motif. This, therefore, would place a considerable search burden upon the examiner.

The requirement is still deemed proper and is therefore made FINAL.

Specification

2. The title of the invention is objected to. Applicant is reminded of the following.

- (a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.

Appropriate correction is required. In the event of the failure by Applicant to provide a new title, one will be chosen by the Examiner.

Information Disclosure Statement

3. The information disclosure statement filed 2/25/2002 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Objections

4. Claim 12 is objected to because it contains non-elected subject matter (e.g. parts a-z, aa-mm and oo-aaa).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 19 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claim reads on a method for the prevention of cell death by administering to a patient a protein of claim 13. Thus, the claim reads on preventing all cell death, regardless of the condition of the patient. However, the scope of the instant claim is not commensurate with the enablement of the instant disclosure, because practice of the claimed invention means that it is possible to prevent cell death completely. For instance, in a patient who has pancreatic cancer, the administration of a protein from claim 13 in a therapeutically effective dose to said patient will not prevent cell death caused by the cancer. Therefore, it would require from one of ordinary skill in the art undue experimentation to make and use the claimed invention.

The considerable breadth of claim 19 warrants this enablement rejection. However, a simple change of wording to, for example, 'A method for decreasing apoptosis, wherein said method.....' would overcome this rejection.

Conclusion


7. Claim 19 is rejected. Claims 13-16 are allowed. Claim 12 is objected to. Claim 12 would be allowable if rewritten to remove the non-elected subject matter.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzanne M. Mayer, Ph.D. whose telephone number is 571-272-2924. The examiner can normally be reached Monday to Friday from 8.30am-5.00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SMM
18 June, 2004


ROBERT A. WAX
PRIMARY EXAMINER